

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

MUTUAL PHARMACEUTICAL
COMPANY, INC., et al.,

Plaintiffs,

-v-

WATSON PHARMACEUTICALS,
INC., et al.,

Defendants.

Civil Action No. 3:09-cv-5421 (GEB)
(TJB)

Filed Electronically

DEFENDANT WEST-WARD PHARMACEUTICAL CORP.'S

NOTICE OF FILING FDA NOTICE

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Attorneys for Defendant West-Ward Pharmaceutical Corp.

In connection with its Motion for Summary Judgment and supporting brief, (Docket Entry Nos. 265 and 265-2), West-Ward wishes to advise the Court of a notice published today in the Federal Register, by the United States Food & Drug Administration (the “FDA”), announcing its intention to take enforcement action against manufacturers of unapproved colchicine products who continue to manufacture and distribute after a certain grace period. A copy of the notice is attached hereto as Exhibit “A.”

West-Ward does not believe that the FDA’s notice affects the merits of its summary judgment motion, insofar as that motion is premised on Plaintiffs’ unclean hands, based on their identical sales of unapproved colchicine tablets spanning over more than a decade, but is filing this notice in view of its prior representation that FDA had not taken any enforcement action against West-Ward. *See West-Ward Brief in Support of Summary Judgment at 3.*

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/s/ Michael Dore

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Health and Human Services. The four cross-cutting strategic priorities are: (1) Advance Regulatory Science and Innovation, (2) Strengthen the Safety and Integrity of the Global Supply Chain, (3) Strengthen Compliance and Enforcement Activities to Support Public Health, and (4) Expand Efforts to Meet the Needs of Special Populations. The four strategic program goals are: (1) Advance Food Safety and Nutrition, (2) Promote Public Health by Advancing the Safety and Effectiveness of Medical Products, (3) Establish an Effective Tobacco Regulation, Prevention, and Control Program, and (4) Manage for Organizational Excellence and Accountability.

The strategic planning process is an opportunity for FDA to further refine and strengthen the strategic management structure currently in place. For comparison purposes, the current FDA Strategic Action Plan 2007 can be viewed at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/StrategicActionPlan/UCM061415.pdf>.

FDA has made significant progress in its strategic planning efforts. As we build on this progress we look forward to receiving your comments by (see **DATES**). The text of the draft strategic priorities document is available in a "pdf" (portable document format) downloadable format through FDA's Web site: <http://www.fda.gov/AboutFDA/>.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 27, 2010.

Leslie Kux,
Acting Assistant Commissioner for Policy.
[FR Doc. 2010-24603 Filed 9-30-10; 8:45 am]

BILLING CODE 4180-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0257]

Single-Ingredient Oral Colchicine Products; Enforcement Action Dates

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or agency) is announcing its intention to take enforcement action against unapproved single-ingredient oral colchicine products and persons¹ who manufacture or cause the manufacture of such products or their shipment in interstate commerce. Unapproved single-ingredient oral colchicine products have been associated with serious adverse events, including fatalities. Single-ingredient oral colchicine products are new drugs that require approved applications because they are not generally recognized as safe and effective. Currently one firm has obtained approved applications to market single-ingredient oral colchicine for the treatment of acute gout flares, prophylaxis of gout flares, and prophylaxis of attacks of Familial Mediterranean Fever (FMF). All other manufacturers who wish to market single-ingredient oral colchicine products for these or other indications must obtain FDA approval of a new drug application (NDA) or an abbreviated new drug application (ANDAs).

DATES: This notice is effective October 1, 2010. For information about enforcement dates, see **SUPPLEMENTARY INFORMATION**, section III.C.

ADDRESSES: All communications in response to this notice should be identified with Docket No. FDA-2010-N-0257 and directed to the appropriate office listed as follows:

Regarding applications under section 505(b) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(b)): Division of Anesthesia, Analgesia and Rheumatology Products, Office of New Drugs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Silver Spring, MD 20993-0002.

All other communications: See the **FOR FURTHER INFORMATION CONTACT** section of this document.

¹A "person" includes individuals, partnerships, corporations, or associations (section 201 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(e)).

FOR FURTHER INFORMATION CONTACT:

Karen Rothschild, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 5237, Silver Spring, MD 20993-0002, 301-796-3689, e-mail: Karen.Rothschild@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Colchicine is an alkaloid of the *Colchicum autumnale* plant, also known as autumn crocus or meadow saffron. Colchicum was initially described in the 1st century A.D. by Dioscorides in the *Materia Medica*. Medical use of colchicum for gout pain dates back to the 6th century. It was used for several centuries, but the use of colchicum in the treatment of gout substantially declined by the 15th century because of its toxicity. Colchicum was reintroduced as a treatment for acute gout beginning in 1763. Colchicine was first isolated from colchicum in 1820 and made available in oral dosage form during the 19th century. Colchicine in oral dosage form is currently marketed in the United States as approved and unapproved products, both as a single ingredient and in combination with probenecid. Colchicine for injection has been available in the United States since the 1950s and has been administered intravenously for the treatment of acute gout flares. In the **Federal Register** of February 8, 2008 (73 FR 7565), FDA announced its intention to take enforcement action against unapproved drug products containing colchicine for injection. Single-ingredient oral colchicine products, the subject of this notice, have also been marketed in the United States without approved applications to treat acute gout flares, and are more commonly marketed in conjunction with uric acid lowering agents for the daily prophylaxis of flares of gout. Daily oral colchicine has also been the standard of care since the 1970s for the prophylaxis of attacks of FMF.

One firm, Mutual Pharmaceutical Co., Inc. (Mutual), of Philadelphia, PA, has received approval for three NDAs for single-ingredient oral colchicine. These approvals are: NDA 22-352 for the treatment of FMF,² approved on July 29,

²Because the incidence of FMF in the United States is rare, Mutual sought and was granted orphan drug status for its product covered by NDA 22-352 under section 526 of the act (21 U.S.C. 360bb). The term "orphan drug" refers to a product that treats a rare disease affecting fewer than 200,000 Americans. Enacted in 1983, the intent of the Orphan Drug Act is to stimulate the research, development, and approval of products that treat

2009; NDA 22-351 for the treatment of acute gout flares, approved on July 30, 2009; and NDA 22-353 for the treatment of chronic gout, approved on October 16, 2009. Mutual is marketing these products under the trade name COLCRYS. These approvals were based on extensive evaluation of studies and new data that permitted refinement of dosing regimens and labeling. When used in accordance with the approved labeling, single-ingredient oral colchicine was found to be well-tolerated and safe when taken at therapeutic doses and with appropriate dose reductions in susceptible populations or with potentially interacting drugs.

II. Safety Issues in the Use of Single-Ingredient Oral Colchicine Products

The most frequent adverse effects of oral colchicine in therapeutic doses are those involving the gastrointestinal tract, with the most common adverse events being diarrhea, nausea and vomiting, abdominal pain, and cramping. These events are often the first indication that colchicine therapy may need to be stopped or the dose reduced. Overdose with colchicine is uncommon, despite its narrow therapeutic index and despite wide variation in the dose required for significant morbidity and mortality. Approximately 20 adverse event reports including 5 deaths are reported to the agency on average per year. However, above the typical therapeutic doses (which range from a 2.4-milligram (mg) maximum daily chronic dose to the 4.8-mg maximum acute dose), there does not seem to be any clear separation between nontoxic, toxic, or lethal doses of colchicine. Overall, FDA is aware of 751 reports of adverse events associated with colchicine toxicity, including 169 deaths associated with oral colchicine, through June 2007.³

There is also evidence supporting a potentially lethal interaction between P-glycoprotein (P-gp) inhibitors/strong cytochrome P450 3A4 (CYP3A4) inhibitors (such as clarithromycin) and colchicine. Although these interactions have been published in the medical literature, fatal interactions continue to

be reported to postmarketing adverse event databases. Postmarketing adverse event databases, including FDA's AERS database, reveal that half of non-overdose colchicine fatalities are related to the concomitant use of colchicine and clarithromycin. This information suggests that despite the literature, awareness regarding colchicine interactions may not be widespread in the healthcare community. Another variable in this equation is that interactions are potentially more severe and lethal in patients with an underlying susceptibility. Based on the published literature, a 4-fold decrease in colchicine clearance is noted in severely renally impaired subjects undergoing hemodialysis compared to healthy volunteers. A 2.5- to 10-fold lower clearance has been reported in cirrhotic patients when compared to healthy subjects. No pharmacokinetic studies have been performed in the elderly or in pediatric patients. However, because the elderly are more likely to have significant renal or hepatic impairment, as a whole, they are more at risk. In light of these safety concerns, there are specific dose modification and reduction recommendations in the recently approved colchicine labeling pertaining to drug interactions and to patients with renal impairment. Furthermore, a new clinical trial in acute gout that was conducted in support of the NDA found that a lower dose of oral colchicine than had been considered the standard of care was just as effective for the treatment of an acute gout flare, and resulted in fewer adverse events. The approved labeling for oral colchicine reflects this newly discovered information.

In general, the labeling for unapproved single-ingredient oral colchicine products listed with FDA under section 510(j) of the act (21 U.S.C. 360(j)) does not reflect the most current data regarding the safety and effectiveness of single-ingredient oral colchicine. As noted previously in this document, the newly approved labeling reflects the new dosing for acute gout flares. Additionally, based on pharmacokinetic studies conducted in support of the approved NDAs, new specific-dose modification and reduction recommendations are provided in the approved colchicine labeling for its use with drugs that use certain enzymes, such as CYP3A4 or P-gp, for their metabolism or absorption. Because no applications have been submitted to and reviewed by FDA for the unapproved single-ingredient oral colchicine products, the safety and

effectiveness of these unapproved products cannot be assured.

The expected risks associated with use of oral products that contain single-ingredient colchicine are potentially greater for unapproved products because the quality, safety, and efficacy of unapproved formulations have not been demonstrated to FDA. For example, the ingredients and bioavailability of unapproved products have not been submitted for FDA review, nor has FDA had the opportunity to assess the adequacy of their chemistry, manufacturing, and controls specifications. Further, as noted previously, a clinical trial revealed that a substantially lower dose of colchicine is as effective as the higher dose traditionally considered to be the standard of care, with significantly reduced adverse reactions. Because FDA has not approved the labeling for unapproved single-ingredient colchicine products, their labeling likely does not contain appropriate dosing and drug interaction information.

III. Legal Status

A. Current Status of Single-Ingredient Oral Colchicine

As stated previously, only one firm, Mutual Pharmaceutical, Inc. (Mutual), has obtained approved applications for single-ingredient oral colchicine tablets. Mutual submitted three NDAs for its single-ingredient colchicine tablets: NDA 22-352 for the indication of FMF, which was approved on July 29, 2009; NDA 22-351 for the treatment of acute gout, which was approved on July 30, 2009; and NDA 22-353 for the prevention of gout flares in the chronic treatment of gout, which was approved on October 16, 2009. Mutual is marketing these products under the trade name COLCRYS. As stated previously, because the incidence of FMF in the United States is rare, Mutual sought and was granted orphan drug status for its product covered by NDA 22-352 under section 526 of the act.

Unapproved single-ingredient oral colchicine tablets are also available on the market. The agency reviewed the labeling of unapproved colchicine products listed with FDA under section 510(j) of the act. In general, labeling for the unapproved products does not reflect the most current data regarding single-ingredient oral colchicine. As noted previously, the newly approved labeling reflects the new dosing for acute gout flares. Based on pharmacokinetic studies, new specific-dose modification and reduction recommendations are provided in the approved colchicine label for its use

³ rare diseases. Under this law, which amended the act and is provided in sections 525 through 529 (21 U.S.C. 380aa through 380de), a firm that receives approval for a product designated as an orphan drug receives for the product a special period of exclusivity of 7 years after the date of approval, during which the agency will not approve another application for the same drug for the same condition submitted by another applicant (see 21 CFR 316.3).

³ Data in the current system (AERS) date back to when the adverse event reporting system was first implemented in 1969.

with drugs that use certain enzymes, such as CYP3A4 or P-gp, for their metabolism or absorption. Because no applications have been filed and reviewed by the agency for the unapproved products, the safety and effectiveness of these products cannot be ensured.

B. Single-Ingredient Oral Colchicine Products Are New Drugs Requiring Approved Applications

Based on both the safety considerations previously described and the absence of published literature documenting that single-ingredient oral colchicine is safe and effective, unapproved single-ingredient oral colchicine is not generally recognized as safe and effective for any indication including treatment of acute gout flares or for the daily prophylaxis of gout. Agency review of individual applications to ensure appropriate manufacturing and labeling is required to ensure the safe and effective use of the drug. Therefore, single-ingredient oral colchicine is regarded as a new drug as defined in section 201(p) of the act (21 U.S.C. 321(p)) and is subject to the requirements of section 505 of the act. As set forth in this notice, approval of an NDA or ANDA under section 505 of the act is required as a condition for manufacturing or marketing all single-ingredient oral colchicine products. Any person who submits an application for a single-ingredient oral colchicine product but has not received approval must comply with this notice.

C. Notice of Enforcement Action

Although not required to do so by the Administrative Procedure Act, the act, or any rules issued under its authority, or for any other legal reason, FDA is providing this notice to persons who are marketing unapproved single-ingredient oral colchicine products that after the dates identified in this notice, the agency intends to take enforcement action against such products and those who manufacture them or cause them to be manufactured or shipped in interstate commerce.

Manufacturing or shipping unapproved single-ingredient oral colchicine products can result in enforcement action, including seizure, injunction, or other judicial or administrative proceedings. Consistent with policies described in the agency's guidance entitled "Marketed Unapproved Drugs—Compliance Policy Guide" (the Marketed Unapproved Drugs CPG), the agency does not expect to issue a warning letter or any other further warning to firms marketing unapproved single-ingredient oral

colchicine products prior to taking enforcement action. The agency also reminds firms that, as stated in the Marketed Unapproved Drugs CPG, any unapproved drug marketed without a required approved drug application is subject to agency enforcement action at any time. The issuance of this notice does not in any way obligate the agency to issue similar notices or any notice in the future regarding marketed unapproved drugs.⁴

As described in the Marketed Unapproved Drugs CPG, the agency may, at its discretion, identify a period of time during which the agency does not intend to initiate an enforcement action against a currently marketed unapproved drug solely on the ground that it lacks an approved application under section 505 of the act. With respect to unapproved single-ingredient oral colchicine products, the agency intends to exercise its enforcement discretion for only a limited period of time because single-ingredient oral colchicine products are drugs with potential safety risks and, in light of the fact that the agency has approved applications for single-ingredient oral colchicine products for the treatment of acute gout flairs, prophylaxis of gout flares, and prophylaxis of attacks of FMF, the continued marketing of unapproved single-ingredient oral colchicine products is a direct challenge to the drug approval process. Therefore, the agency intends to implement this notice as follows.

This notice is effective October 1, 2010. FDA intends to take action to enforce section 505(a) of the act against any unapproved single-ingredient oral colchicine products that are not listed with FDA in full compliance with section 510 of the act before September 30, 2010, and that are manufactured, shipped, or otherwise introduced or delivered for introduction into interstate commerce by any person on or after October 1, 2010. FDA also intends to take action to enforce section 505(a) of the act against any unapproved single-ingredient oral colchicine products that have a National Drug Code (NDC) number listed with FDA in full compliance with section 510 of the act but were not being commercially used or sold⁵ in the United States on September 30, 2010, and that are manufactured, shipped, or otherwise introduced or delivered for introduction

into interstate commerce by any person on or after October 1, 2010.

However, for unapproved single-ingredient oral colchicine products that are commercially used or sold in the United States, have an NDC number listed with FDA, and are in full compliance with section 510 of the act before September 30, 2010 ("currently marketed and listed"), the agency intends to exercise its enforcement discretion as follows. FDA intends to initiate enforcement action against any currently marketed and listed unapproved single-ingredient oral colchicine products that are manufactured on or after November 15, 2010, or that are shipped on or after December 30, 2010.⁶ Further, FDA intends to take enforcement action against any person who manufactures or ships such products after these dates. Any person who has submitted or submits an application for a single-ingredient oral colchicine product but has not received approval must comply with this notice.

The agency, however, does not intend to exercise its enforcement discretion as outlined previously if either of the following applies: (1) A manufacturer or distributor of an unapproved single-ingredient oral colchicine product is violating any other provisions of the act (including but not limited to violations related to FDA's current good manufacturing practices, adverse drug event reporting, labeling or misbranding requirements) or (2) it appears that a firm, in response to this notice, increases its manufacture or interstate shipment of unapproved single-ingredient oral colchicine products above its usual volume.

Nothing in this notice, including FDA's intent to exercise its enforcement discretion, alters any person's liability or obligations in any other enforcement action or litigation, or precludes the agency from initiating or proceeding with enforcement action in connection with any other alleged violation of the act, whether or not related to an unapproved drug product covered by this notice. Similarly, a person who is

⁴ If FDA finds it necessary to take enforcement action against a product covered by this notice, the agency may take action relating to all of the defendant's other violations of the act at the same time. For example, if a firm continues to manufacture or market a product covered by this notice after the applicable enforcement date has passed, to preserve limited agency resources, FDA may take enforcement action relating to all of the firm's unapproved drugs that require applications at the same time (see, e.g., *United States v. Sage Pharmaceuticals*, 210 F. 3d 475, 479–480 (5th Cir. 2000) (permitting the agency to combine all violations of the act in one proceeding, rather than taking action against multiple violations of the act in "piecemeal fashion")).

⁴ The agency's general approach for dealing with these products in an orderly manner is spelled out in the Marketed Unapproved Drugs CPG.

⁵ For the purpose of this notice, the term "commercially used or sold" means that the product has been used in a business or activity involving retail or wholesale marketing and/or sale.

or becomes enjoined from marketing unapproved drugs may not resume marketing of unapproved single-ingredient oral colchicine based on FDA's exercise of enforcement discretion as set forth in this notice.

Drug manufacturers and distributors should be aware that the agency is exercising its enforcement discretion as described previously only in regard to unapproved single-ingredient oral colchicine products that are marketed under an NDC number listed with the agency in full compliance with section 510 of the act before September 30, 2010. As previously stated, unapproved single-ingredient oral colchicine products that are currently marketed but not listed with the agency on the date of this notice must, as of the effective date of this notice, have approved applications before shipment in interstate commerce.

D. Discontinued Products

Some firms may have previously discontinued the manufacturing or distribution of products covered by this notice without removing them from the listing of their products under section 510(j) of the act. Other firms may discontinue manufacturing or marketing listed products in response to this notice. Firms that wish to notify the agency of product discontinuation should send a letter, signed by the firm's chief executive officer, fully identifying the discontinued product(s), including the product NDC number(s), and stating that the product(s) has (have) been discontinued. The letter should be sent electronically to edrls@fda.hhs.gov. Firms should also update the listing of their products under section 510(j) of the act to reflect discontinuation of unapproved single-ingredient colchicine products. FDA plans to rely on its existing records, the results of a subsequent inspection, or other available information when we evaluate whether to initiate enforcement action.

This notice is issued under the act (sections 502 (21 U.S.C. 352) and 505) and under authority delegated to the Deputy Commissioner, Office of Policy, Planning and Budget under section 1410.21 of the FDA Staff Manual Guide.

Dated: September 27, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010-24684 Filed 9-30-10; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS-2010-0080]

Critical Infrastructure Partnership Advisory Council (CIPAC)

AGENCY: National Protection and Programs Directorate, DHS.

ACTION: Notice of CIPAC meeting.

SUMMARY: The CIPAC will meet on October 13, 2010 in Bethesda, MD. The meeting will be open to the public.

DATES: The CIPAC will meet Wednesday, October 13, 2010 from 8:30 a.m. to 12:30 p.m. Please note that the meeting may adjourn early if the committee has completed its business. For additional information, please consult the CIPAC Web site, <http://www.dhs.gov/cipac>, or contact the CIPAC Secretariat by phone at 703-235-3999 or by e-mail at cipac@dhs.gov.

FOR FURTHER INFORMATION CONTACT: Renee Murphy, Section Chief Partnership Programs, Partnership and Outreach Division, Office of Infrastructure Protection, National Protection and Programs Directorate, United States Department of Homeland Security, Mail Stop 0607, 245 Murray Lane, SW., Washington, DC 20528-0607, telephone 703-235-3999 or via e-mail at CIPAC@dhs.gov.

Responsible DHS Official: Renee Murphy, Section Chief Partnership Programs, Partnership and Outreach Division, Office of Infrastructure Protection, National Protection and Programs Directorate, United States Department of Homeland Security, Mail Stop 0607, SW., 245 Murray Lane, SW., Washington, DC 20528-0607, telephone 703-235-3999 or e-mail at CIPAC@dhs.gov.

SUPPLEMENTARY INFORMATION: CIPAC represents a partnership between the Federal Government and critical infrastructure owners and operators and provides a forum in which they can engage in a broad spectrum of activities to support and coordinate critical infrastructure protection.

The CIPAC will meet to discuss issues relevant to the protection of critical infrastructure. The October 13, 2010 meeting will include panel discussions between participating Sectors regarding Regionalization and Resilience and Information Sharing.

Procedural: While this meeting is open to the public, participation in the CIPAC deliberations is limited to committee members, DHS officials, and persons invited to attend the meeting for special presentations.

Information on Services for Individuals with Disabilities: For information on facilities or services for individuals with disabilities or to request special assistance at the meeting, contact the CIPAC Secretariat at 703-235-3999 as soon as possible.

Signed: September 24, 2010.

Renee Murphy,

Alternate Designated Federal Officer for the CIPAC.

[FR Doc. 2010-24670 Filed 9-30-10; 8:45 am]

BILLING CODE 9110-9P-P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

Agency Information Collection Activities: New Information Collection; Comment Request

ACTION: 60-day notice of information collection under review: E-Verify Self Check Program (Internal File Number OMB-59).

The Department Homeland Security, U.S. Citizenship and Immigration Services (USCIS) will be submitting the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for sixty days until November 30, 2010.

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Department of Homeland Security (DHS), USCIS, Chief, Regulatory Products Division, Clearance Officer, 20 Massachusetts Avenue, NW., Washington, DC 20529-2020. Comments may also be submitted to DHS via facsimile to 202-272-8352 or via e-mail at rfs.regs@dhs.gov. When submitting comments by e-mail, please make sure to add Control No. OMB-59 in the subject box. Written comments and suggestions from the public and affected agencies concerning the collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies estimate of the burden of the